DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

January 6, 2022

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St.
Suite 1701
New York, NY 10001

Re: U01AI151797 and U01AI153420

Dear Drs. Chmura and Daszak:

I am writing to inform you of the actions that the National Institutes of Health (NIH) is taking with respect to grants administration at EcoHealth Alliance (EcoHealth). Pursuant to 45 C.F.R. § 75.207 and the NIH Grants Policy Statement Chapter 8.5, NIH is imposing specific award conditions on EcoHealth's active awards, U01AI151797 and U01AI153420. EcoHealth has demonstrated a history of failure to comply with several elements of the terms and conditions of grant awards not only for these active awards, but also for the suspended award, R0AI110964. Specifically, we have identified deficiencies in the timely submission of financial and Research Performance Progress Reports (RPPR), compliance with the Federal Funding Accountability and Transparency Act (FFATA) via FFATA Subaward Reporting System (FSRS), and other monitoring requirements.

NIH has reviewed the materials you provided in prior correspondence and determined that EcoHealth's subaward agreements do not contain required components, as outlined in 45 C.F.R. § 75.352 and the NIH GPS 15.2.1, and are out of compliance. Specifically:

Written Agreement Requirements	**Compliance - Status**
All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award. ("The terms and conditions of Federal-awards (including [45 CFR 75]) flow down to subawards to subrecipients" 45 CFR 75.101(b))	Non-compliant: Not provided.
Any additional requirements that the pass-through entity imposes on the subrecipient in order for the pass-through entity to meet its own responsibility to the HHS awarding agency including identification of any required financial and performance reports.	Non-compliant: The agreements lacked clear requirements for when financial and performance reports are due, and what must be included in them. In addition, the recipient failed to submit the reports, when requested.
A requirement that the subrecipient permit EcoHealth and auditors to have access to the subrecipient's records and financial statements as necessary for EcoHealth to meet the requirements under 45 CFR part 75.	Non-compliant: Not provided.
Procedures for directing and monitoring the research effort.	Non-compliant: Not provided.

If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that the subrecipient's Investigators are subject to the Financial Conflict of Interest policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution.	Non-compliant: Subrecipient FCOI policy not provided, nor was there a certification as part of the written agreement demonstrating compliance with the 2011 revised FCOI regulation (42 CFR 50 Subpart F).
A provision addressing ownership and disposition of data produced under the consortium agreement. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.	Non-compliant: Not provided.
A provision making the NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements-Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the recipient can fulfill its responsibilities to NIH.	Non-compliant: Not provided.
Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates).	Non-compliant: The agreement does not incorporate applicable public policy requirements.

NIH further identified non-compliance within EcoHealth's subaward agreement and invoices with the Wuhan Institute of Virology on grant R01AI110964, where it showed that EcoHealth did not charge the correct Facilities and Administrative (F&A) rate of 8 percent for the cost of compliance (see NIH GPS 16.6) which is required for all foreign awards. NIH identified that an inappropriate F&A was charged at a rate of 11 percent for years 2-5 of the subaward agreement.

When NIH identifies a recipient's history of non-compliance with the general or specific terms and conditions of NIH grant awards, NIH may take proactive actions to protect the Federal government's interests and may impose additional specific award conditions as needed (see 45 CFR 75.207 and NIH GPS 8.5). Given the non-compliance in the aforementioned areas, NIH is implementing specific award conditions (SAC) on all active awards to EcoHealth (U01AI151797 and U01AI153420), as follows.

- The expanded authority for automatic no-cost extensions is withdrawn. This will require that EcoHealth request and receive written prior approval from the appropriate NIH awarding Institute or Center (IC) before any extensions of the final budget period.

- Automatic carryover authorities are withdrawn. This will require EcoHealth to request and receive written approval to carry over any unobligated balances on all awards prior carrying over unobligated balances from one budget period to any subsequent budget period.
- EcoHealth is required to submit semi-annual RPPRs and Federal Financial Reports to the awarding IC.

EcoHealth must develop and successfully implement a Corrective Action Plan (CAP) for these awards with milestones to address and correct the deficiencies noted in this letter. The Corrective Action Plan, at a minimum, must include the following:

- Show proof of written policies and procedures for the development and issuance of subaward agreements, and a plan for revising the policies to address any deficiencies. The policy must include procedures for ensuring the appropriate F & A rate is applied to all subawards.
- Provide NIH with copies of updated subaward agreements for all active awards that correct the deficiencies noted above and demonstrate compliance with the NIH GPS 15.2.1 Written Agreement. The subaward agreements must state the correct F&A rate which, for foreign subrecipients is 8% (see NIH GPS 16.6).
- Show proof of written policies and procedures for timely submission of financial and progress reporting, and a plan for revising the policies to address any deficiencies.
- Show proof of written policies and procedures for subaward reporting as required by FFATA (see NIH GPS 8.4.1.5.5), and a plan for revising the policies to address any deficiencies.
- Provide NIH with copies of FSRS reporting for all subawards.

Once NIH reviews the CAP and determines that EcoHealth has successfully implemented it and has corrected the deficiencies noted in this letter, we will remove the SACs on the active awards without additional action on the part of EcoHealth. If we determine that additional information and actions are required, we will notify EcoHealth so that we can ensure compliance and, ultimately, remove the SACs.

Please provide the CAP to me within 30 days of receipt of this letter. If you have questions or would like to request reconsideration of the specific award conditions on the active awards, please feel free to contact me via email.

Sincerely,

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2022.01.06 16:25:16 -05'00'

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